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REMARKS

This Paper is respectfully submitted in response to the Office Action rendered in the above-identified patent application on September 27, 2005. It is timely submitted in view of the Petition for Extension of Time submitted concurrently herewith.

Claims 1-22 and 68-70 are pending. Claim 14 has been amended with this Paper to correct an obvious omission of the word "and".

The Office Action of September 27, 2005 rejected claims 1-3, 6, 7, 9, 16, and 19 under 35 U.S.C. 102(e), as being anticipated by Costanzo (US 6,323,219). (Office Action page 2) The basis for this rejection was given as follows:

Costanzo discloses method and composition for "bringing about skin pigmentation and/or for causing skin depigmentation;" the methods and composition of Costanzo can be used as depigmenting compositions, darkening compositions and as compositions for preventing and/or treating immunomediated inflammatory diseases such as asthma and allergic rhinitis (abstract). The composition of Costanzo contains serine protease inhibitors that may be obtained from extracts of Solanaceae, Gramineae, Cucurbitaceae and Leguminosae (column 8, lines 52-67); soybean milk also contains serine protease (column 9, lines 47-53; column 28, lines 50-67).

Costanzo specifically discloses topically applying to mammalian skin pharmaceutical or cosmetic compositions in an amount effective to effect changes in pigmentation (column 10, lines 13-17) and soybean milk or other formulations derived directly from legumes is applied to the mammalian skin (column 9, lines 47-52). Costanzo lists gray hair as one of the skin disorders treatable with the composition (column 30, lines 14-27).

Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

As set forth previously in Papers submitted on September 27, 2004 and February 8, 2005, applicants again respectfully submit that Costanzo neither suggests nor describes methods for using the composition of applicants' invention to effect needed changes in hair. As set forth in the claims, Applicants make clear that according to applicants' methods, the composition is to be applied to mammalian hair in need of a change in appearance.

The statement from Costanzo cited and relied upon in the Office Action is as follows:

Skin disorders include unwanted pigmentation, unwanted depigmentation, psoriasis, rashes, and certain physical skin imperfections (e.g., wrinkles). In one

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specific example, vitiligo patients are treated with melanin (via liposomes or plain) together with a phagocytosis-increasing agent (e.g., SLIGRL) to darken the light spots. Alternatively, they are treated with Compound I to lighten the darker sites (see U.S. Ser. No. 09/110,409, filed Jul. 6, 1998). *In an example related to skin disorders, gray hair is treated with melanin (plain or liposome-delivered) and phagocytosis-increasing agent (e.g., SLIGRL), ideally in a shampoo or cream.* Central nervous system disorders include, without limitation, Alzheimer's disease and other senile plaque disorders (treated via up-regulating the phagocytosis of amyloid fibrils), depression, phobic disorders, and other disorders resulting from secondary effects of benzodiazepine treatment. [Costanzo, col. 30, l. 14-32] (emphasis added)

The Office Action admits that Costanzo does not disclose that the composition set forth therein would affect hair:

Thus, although Costanzo does not specifically disclose that the composition has an effect on hair growth, since the instant claim 1 and Costanzo apply the same composition to the skin, the effect on the skin from both compositions would be the same. [Office Action, p. 3]

Applicants respectfully submit that Costanzo neither explicitly nor inherently describes or suggests the methods and compositions of applicants' invention. As set forth in the ensuing discussion, Costanzo's only reference to use of *any* composition on hair relates to a composition *different* from that set forth in applicants' claimed invention. Moreover, Costanzo's topical use on the skin of compositions containing soymilk, for example, would not have inevitably led to inherent use of the methods of applicants' claimed invention.

The only suggestion in Costanzo for use of compositions on hair requires treatment of gray hair with melanin and a phagocytosis-increasing agent, SLIGRL. SLIGRL is not a member of the botanical families set forth in the compositions of applicants' invention. It is a *phagocytosis enhancer* applied in conjunction with melanin, *not* a serine protease inhibitor. Thus, Costanzo does not suggest or describe the application of compositions of applicants' invention on hair.

Furthermore, as set forth in the Office Action, Costanzo relates to a method and composition for "bringing about *skin* pigmentation and/or for causing *skin* depigmentation;" ... [Office Action, p. 3] (emphasis added). The Office Action utilizes Costanzo's "topically applying to mammalian skin pharmaceutical or cosmetic

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composition in an amount effective to effect changes in pigmentation...and soybean milk or other formulations derived directly from legumes is applied to the mammalian skin..." [Office Action, p. 3] as the basis for inherency in support of the rejection under 35 U.S.C. 102(e). However, even if one were to follow Costanzo in applying compositions topically to skin, the result would not *inevitably* be that of the methods of applicants' invention, as required in order to serve as a basis for an inherency rejection.

All pigment in the hair arises from the hair bulb from a line of melanocytes that produces the melanosomes for the keratinocytes of the hair shaft. Pigment is added to the hair only during the growing or anagen stage. There is no pigment production during the resting or telogen stage. The perceived color of hair is the result of structural proteins, the luminance and color dilution. [*Physiology of the Skin II*, Peter Pugliese, Chapter 5, p. 54 (2001)]. Thus, mere application of the compositions set forth in Costanzo to skin at certain times during the life cycle of a hair would not necessarily inevitably effect changes in a hair that may be located in proximity to the skin being treated if they are applied indiscriminantly during the life cycle.

Moreover, Costanzo's only reference to hair itself relates to darkening gray hair, but not to reducing hair color or visibility. It clearly does not mention any effect on hair growth parameters. Indeed, the only effect on gray hair set forth in Costanzo is providing *exogenous* melanin to "stain" gray hair. In contrast, the methods of applicants' invention perform the opposite, i.e., reducing hair visibility by reducing growth and *endogenous* melanin production, or reducing hair growth to manage making it grow slower, and appear thinner.

Applicants respectfully submit that Costanzo does not teach the methods of claims 1-3, 6, 7, 9, 16 or 19. These claims are directed to methods for effecting changes in mammalian hair appearance and hair pigmentation, and reducing hair growth, and hair follicle and hair shaft size by a topical application of a topically active composition containing one or more compounds derived from one or more botanical families leguminosae, solanaceae, gramineae and cucurbitaceae. Costanzo does not meet these limitations and therefore does not anticipate the invention. Nor would it be inherent that the invention of Costanzo would affect the hair as required by the rejected claims.

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Therefore, Applicants respectfully request reconsideration of the rejection under 35 U.S.C. 102(e) in view of Costanzo in view of the foregoing discussion.

The Office Action rejected claims 4, 5, 8, 10-14, 16-18, 20-22 and 68-70 under 35 U.S.C. 103(a) as being unpatentable over Costanzo (US 6,323,219) in view of Matsuura et al (US 6139899) ("Matsuura") (Office Action, p. 4.) The basis for the rejection of claim 4 and 5 was given as follows:

The teaching of Costanzo is discussed above and Costanzo discloses the method of the instant claims, that is, topically applying a composition comprising extracts from the plants Solanaceae, Gramineae, Cucurbitaceae and Leguminosae as discussed above. Regarding claim 4 and 5, there is no showing demonstrating that the amount of the inhibitor provides unusual results. [Office Action, p. 4]

The Office Action further indicated that Costanzo was relevant to claims 11-14, 16-18 and 20-22 "since the composition of the prior art is applied to the skin, the composition would inherently exhibit the properties of the composition on the skin". [Office Action, p.

4]. The basis for the rejection for claims 68-70 was given as follows:

Regarding new claims 68-70, it is respectfully noted that the instant method involves application of the composition to the skin to effect inhibition of hair growth, reduction of hair follicle and hair shaft and reduction of hair pigmentation, the prior art applies a composition containing serine protease inhibitor and would be expected that composition similar to the composition of the instant claims would have the same effect on the skin or hair when topically applied to the skin. Thus, in the alternate, it would have been obvious for the same/similar composition to have the same/similar effect on the skin and on the hair. [Office Action, pp. 4-5]

The basis for the rejection for claims 8 and 10 was given as follows:

Regarding claims 8-10, Costanzo does not disclose that the composition comprising the plant extracts contain isoflavones. However, the composition of the prior art Costanzo contains soybean milk extract. But it is known in the prior art, for example, Matsuura, that soybean milk contains isoflavones. Matsuura discloses the presence of isoflavones in soybean milk (abstract; see whole document). [Office Action, p. 5]

Applicants respectfully request reconsideration of the rejection under 35 U.S.C. 103(a) in view of the ensuing discussion.

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Clarification is respectfully requested as to the rejection of claims 8 and 10. Office Action, page 5 has the rejection as claim 8-10, which would include claim 9. The rejection as initially stated section 6 on page 4 does not include claim 9.

As discussed above, Costanzo does not disclose or suggest the methods or composition of applicants' claimed invention, explicitly or inherently. For the same reasons set forth above in connection with applicants' discussion of Costanzo, one of ordinary skill in the art would not have been led to the methods or compositions of applicants' invention by Costanzo: (a) the only suggestion to use the compositions of Costanzo on hair require both melanin and SLIGRL, *not* the compositions of applicants' invention; and (b) topical use of compositions set forth in Costanzo would not have inherently resulted in the methods of applicants' invention.

Applicants further respectfully request reconsideration of the rejection of claims 4 and 5, which further claim a range of an amount of serine protease inhibitor in the compositions of applicants' invention. Likewise, applicants respectfully request reconsideration of the rejection of claims 11-14, 16-18 and 20-22 under 35 U.S.C. 103(a).

Claims 68-70 relate to a method for inhibiting mammalian hair growth, reducing hair follicle and hair shaft size, and reducing hair pigmentation and involves application of the composition such that it permeates into the hair follicle. Costanzo does not disclose or suggest the use of his composition to effect hair pigmentation as discussed above. Costanzo also does not disclose or suggest methods of effecting change in hair growth, reducing hair follicle and hair shaft size. Therefore, applicants respectfully request reconsideration of the rejection of claims 68-70 under 35 U.S.C. 103(a).

Regarding Claims 8 and 10, the Office Action acknowledges that Costanzo does not disclose that the composition comprising the plant extracts contains isoflavones. [Office Action, p. 5]. To overcome this acknowledged gap, the Office Action initially cites Costanzo as containing soybean milk. The Office Action further cites Matsuura as disclosing that soybean milk contains isoflavones. [Office Action, p. 5]

Applicants respectfully submit that Costanzo neither describes nor suggests the methods of applicants' invention set forth in claim 1, from which claims 8 and 10 depend. Combining Costanzo with Matsuura would not overcome this deficiency. Nowhere does Matsuura suggest or describe a combination of isoflavones and the

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compositions set forth in claim 1. Nor does Matsuura provide motivation for combining the subject matter therein with that of Costanzo to lead one of ordinary skill in the art to the methods and compositions of applicants' invention. In view of the foregoing, applicants respectfully request reconsideration of the rejection of claims 4, 5, 8, 10-14, 16-18, 20-22 and 68-70 under 35 U.S.C. 103(a).

Applicants respectfully request reconsideration of the rejections set forth in the Office Action of September 27, 2005. An early allowance is earnestly solicited.

Respectfully submitted,

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DATE: January 27, 2006